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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,774	11/08/2000	Alessandro Sette	18623006240	3936

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EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/23/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/709,774

Applicant(s)

SETTE ET AL.

Examiner

F. Pierre VanderVegt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18-65 is/are pending in the application.
- 4a) Of the above claim(s) 27-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other:

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### DETAILED ACTION

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

This application is a continuation-in-part of U.S. Application Serial Number 08/305,871, which is a continuation-in-part of U.S. Application Serial Number 08/121,101, and is a continuation-in-part of U.S. Application Serial Number 08/788,822, which claims the benefit of the filing date of provisional applications 60/082,250, 60/101,580 and 60/010,510.

Claims 1-17 have been canceled previously.

Claims 18-65 were previously added and are currently pending.

Claims 27-65 have previously been withdrawn from prosecution.

**Claims 8-26 are the subject of examination in the present Office Action.**

### *Priority*

4. Applicant is not entitled to priority to 08/305,871 due to lack of support for the pending claims. Applicant's arguments filed June 30, 2003 have been fully considered but they are not persuasive. Applicant asserts that the present application is entitled to the filing date of the '871 application because, in part, "description of the pan DR binding peptides can be found, *e.g.*, on page 4, lines 16-28 of the '871 application." However, for the same reasons stated *supra* in section 3, the identical specification of the '871 application discloses "R<sub>1</sub> is a D-amino acid followed by alanine or lysine" and "R<sub>5</sub> consists of 2 to 4 amino acids followed by a D-amino acid where each of the 2 or 4 amino acids is independently selected from the group consisting of alanine, serine and valine" and does not support the recitation of "an amino acid" for both R<sub>1</sub> and R<sub>5</sub>. accordingly, present claims 18-26 are entitled only to the filing date of the instant application, which is November 8, 2000.

1. The following represent new grounds of rejection and objection and result in the present Office Action being made **Non-Final**.

*Specification*

2. The disclosure is objected to because of the following informalities:

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence. See, for example, page 5, lines 1-12, where a number of sequences are disclosed without sequence identifiers. If sequence identifiers have not been established for the sequences, Applicant must amend both the computer readable form (CRF) and the paper copy of the sequence listing, as well as provide the statement that the paper copy and the CRF are the same. Irrespective of whether sequence identifiers have already been established for these sequences, Applicant should state in section <223> of the sequence descriptor that the amino acid residues in the first and last positions of the peptide sequence are D-amino acids.

Appropriate correction is required.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 18-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Base claim 18, first entered as a new claim in the preliminary amendment filed November 8, 2000, is drawn to a polynucleotide encoding a fusion protein which comprises a pan-DR binding peptide of the formula  $R_1-R_2-R_3-R_4-R_5$ , wherein " $R_1$  is an amino acid followed by an alanine or lysine" and " $R_5$  consists of 2 to 4 amino acids followed by an amino acid wherein each of the 2 to 4 amino acids is independently selected from the group consisting of alanine, serine and valine." The recitation of "an amino acid" for both  $R_1$  and  $R_5$  is not supported by the specification or claims as originally filed and constitutes new matter.

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In the remarks accompanying the preliminary amendment filed November 8, 2000 Applicant positions that "[a]ll support" for the new claims is "provided with reference to the '142 patent" [a.k.a., U.S. Patent No. 5,736,142]. It is acknowledged that the '142 patent was issued from the parent application 08/305,871 and that the specification of the instant application is identical to the specification of the '871 application as originally filed on September 14, 1994. However, it is improper to rely upon the citation of passages in the '142 patent for support of amendments to the instant specification and claims. Support should be pointed out within the instant specification and/or claims as originally filed.

In the present case, the specification at page 4, lines 16-36, discloses "R<sub>1</sub> is a D-amino acid followed by alanine or lysine" and "R<sub>5</sub> consists of 2 to 4 amino acids followed by a D-amino acid where each of the 2 or 4 amino acids is independently selected from the group consisting of alanine, serine and valine." The specification does not provide other, alternative, definitions for R<sub>1</sub> and R<sub>5</sub>. Applicant contends in the remarks accompanying the preliminary amendment filed November 8, 2000 that because "the pan DR peptides of the invention can be synthesized via recombinant DNA techniques, it is clear that pan DR peptides need not include D-amino acids." However, R<sub>1</sub> and R<sub>5</sub> have been defined in the specification in an absolute, not alternative, manner. Applicant is reminded that obviousness is not the standard for the addition new limitations to the disclosure as filed. Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977). In the instant case, a limitation for either/each of R<sub>1</sub> or/and R<sub>5</sub> to include "an amino acid" which is not "a D-amino acid" may be obvious over recombinant technology but is not supported by the specification or claims as originally filed. Applicant's assertion in the remarks accompanying the preliminary amendment filed November 8, 2000 that "claim 34 of the '142 patent is directed to pan DR peptides with the exact same amino acid sequences recited in claim 78 [sic; claim 18 per Rule 126] of the present application" is acknowledged. However, it is noted that claim 34 of the '142 patent was added during prosecution and was not originally presented in the '871 application from which it issued.

### *Conclusion*

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (703) 305-4441. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00. If attempts to reach the examiner

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by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

F. Pierre VanderVegt, Ph.D. *RV*  
Patent Examiner  
September 22, 2003

  
John J. Doll, Director  
Technology Center 1600